first form to a lymphatic site in an animal and a boosting step wherein the tumor antigen is administered in a second form into a lymphatic site of the animal, where the form of the tumor antigen administered in the priming and boosting steps are different.

REMARKS

Reconsideration of this application, as amended, is respectfully requested. Claim 1 has been amended to more clearly indicate the nature of the invention. This amendment does not add new matter. Applicants address the Examiner's rejections below.

REJECTIONS UNDER 35 U.S.C. § 102(b)

A. Hurpin (Hurpin, et al. Vaccine, 16: 208-215, 1998)

Claims 1, 2, 4-14 and 16 stand rejected under 35 U.S.C. § being anticipated by Hurpin. Applicants respectfully traverse this rejection as described below.

The Examiner alleged that Hurpin teaches the generation of anti-p53 CTL responses in mice following intrasplenic injection of ALVAC-p53, referring for support to page 211 and Figure 1 of Hurpin. Applicants respectfully point out that Hurpin demonstrates only three different routes of *in vivo* administration: intravenous, subcutaneous, and intradermal. To determine the immunological consequences of these different routes of administration, Hurpin stimulates splenocytes removed from immunized mice with naïve splenocytes infected with NYVAC-p53 *in vitro*. As described on page 209 (MATERIALS AND METHODS, "Determination of specific CTLs against human p53"), "naïve" splenocytes are those removed from a mouse prior to immunization. Following removal from the non-immunized mouse, the cells are infected with NYVAC-p53 *in vitro* and used to stimulate splenocytes removed from mice immunized with ALVAC-p53 intravenously, subcutaneously, or intradermally. Thus, Hurpin does not demonstrate immunization by administration to a lymphatic site and, therefore, does not disclose each and every aspect of the instantly claimed invention. Accordingly, Applicants respectfully request that the rejection of claims 1, 2, 4-14 and 16 as being anticipated by Hurpin be withdrawn.

B. Kundig ("Kunding"; WO 99/02183, Jan. 21, 1999)

Claims 1, 2, 4-14 and 16 stand rejected under 35 U.S.C. § being anticipated by Kundig. Applicants respectfully traverse this rejection as described below

Instant claim 1, as amended, is directed to a method for immunizing a host using a prime-boost protocol in which the tumor antigen is administered in the priming step in one form, and in the boosting step in another form, where the form of antigen in the priming and boosting steps are different. At least two distinct forms of antigen and at least two administration steps are required to practice the instantly claimed method.

In contrast, Kundig relates to the administration of a single form of antigen (i.e., a peptide) in a single-step immunization schedule. For example, Kundig states that the animal "does not have to receive multiple injections" (p. 10) and "the present invention does not require repetitive immunizations" (p. 14). In addition, Kundig is completely silent as to both the use of different forms of antigen in a prime-boost protocol, as instantly claimed. As such, Kundig does not teach each and every feature described in instant claim 1 and does not therefore anticipate the invention of claim 1 or any claims dependent thereon. Accordingly, Applicants respectfully request withdrawal of these rejections.

REJECTIONS UNDER 35 U.S.C. § 103(a)

Claims 1 and 17-19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kundig in view of Zaramba (Cancer Res., 57: 4570-4577 (1997) and Salgaller (Cancer Res., 56: 4749-4757 (1996)). Applicants respectfully traverse these rejections as indicated below.

As discussed above, Applicants maintain that Kundig does not teach or suggest with the use of a multiple-administration immunization procedure or the use of multiple forms of antigen. In contrast, Applicants claim a multi-step immunization procedure using multiple and different forms of antigen. Applicants maintain that one of skill in the art would not have drawn from the Kundig disclosure any suggestion to carry out the instantly claimed method. Neither Zaremaba nor Sangeller satisfy the deficiencies of Kundig with respect to the instantly amended claims. Thus, the Examiner has not set

forth a *prima facie* case of obviousness applicable to the amended claims. In view of the discussion of Kundig, Applicants respectfully suggest that a prima facie case of obviousness cannot be made against the instantly amended claims using Kundig as the primary reference. Accordingly, Applicants respectfully request that these rejections be withdrawn.

CONCLUSIONS

Consideration and entry of these comments and amendments is respectfully requested. Applicants respectfully maintain that claims 1-19 are in condition for allowance, and request that a Notice of Allowance be issued as soon as possible. The Examiner is encouraged to contact the undersigned if it is believed a discussion would expedite prosecution of this application.

Respectfully submitted,

AVENTIS PASTEUR, INC.

Date: May 7, 2002

Patrick J. Halloran
Reg. No. 41, 053

APPENDIX A

1. (Amended) A method for inducing an immune response to a tumor antigen in an animal [to a tumor antigen] comprising [administering an effective amount of] a priming step wherein a tumor antigen [or] is administered in a first form [a nucleic acid sequence encoding a tumor antigen to a lymphatic site in the animal] to a lymphatic site in an animal and a boosting step wherein the tumor antigen is administered in a second form into a lymphatic site of the animal, where the form of the tumor antigen administered in the priming and boosting steps are different.